

Decision Memo for Stem Cell Transplantation (Removal of Coding Information from NCD) (CAG-00193N)

Decision Summary

CMS has determined that it is not appropriate to include Current Procedure Terminology (CPT) codes or International Classification of Diseases-Ninth Revision-Clinical Modification (ICD-9-CM) codes in the NCD for stem cell transplantation. We intend to modify the NCD, currently published in the Coverage Issues Manual (CIM) at 35-30.1, to remove all coding information.

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states the intent of the Centers for Medicare & Medicaid Services (CMS) to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction, program memorandum, CMS ruling or Federal Register Notice giving specific directions to our claims-processing contractors. That issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual or Program Memorandum. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision or Program Memorandum.

To: Administrative File: CAG-00193N Stem Cell Transplantation (Removal of Coding Information from NCD (CAG-00193N)

From:

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Re: Decision Memorandum for Stem Cell Transplantation for Removal of Coding Information from the NCD

Date: October 30, 2003

I. Decision

CMS has determined that it is not appropriate to include Current Procedure Terminology (CPT) codes or International Classification of Diseases-Ninth Revision-Clinical Modification (ICD-9-CM) codes in the NCD for stem cell transplantation. We intend to modify the NCD, currently published in the Coverage Issues Manual (CIM) at 35-30.1, to remove all coding information.

II. Background

In 1978, CMS (then called the Health Care Financing Administration or HCFA) initially published an NCD on stem cell transplantation. At the time, stem cells transplantation was limited to stem cells harvested from bone marrow. Consequently, the title of the NCD was bone marrow transplantation. There have been numerous revisions to the NCD over the years to add both covered and non-covered indications and to clarify existing instructions.

Unlike the majority of NCDs, the stem cell transplantation NCD includes a significant amount of coding information. CPT and ICD-9-CM procedure codes are displayed to identify both allogeneic and autologous stem cell transplantation. Similarly, ICD-9-CM diagnosis codes were included to translate the narrative for covered and non-covered conditions into appropriate coding at the time the instructions on that particular provision were initially drafted.

CPT and ICD-9-CM codes are updated annually. Since stem cell transplantation is a rapidly diffusing technology, numerous changes in coding associated with this technology have taken place since 1978. Additionally, experts in this field expect additional changes in the future. As a result, the coding information presently contained in the NCD as displayed in CIM 35-30.1 is no longer accurate or complete.

III. History of Medicare Coverage

Generally, CMS does not include coding information in NCDs. However, for a brief period of time in an effort to promote consistency in implementation of NCDs, we began including coding information in the NCDs. Shortly thereafter, we re-evaluated this decision to include coding information in coverage decisions. We concluded that such implementation information was more logically and appropriately housed in operational claims processing instructions. We were concerned that the binding nature of NCDs could put providers at a disadvantage if we were to make errors or produce incomplete list of codes in the NCD.

Moreover, both CPT and ICD-9-CM codes are updated annually. We noted that we do not have the resources to completely review all NCDs following each coding update to ensure that they were not affected by the update. Thus, we were concerned that these updates could render our coding advice in the NCDs inaccurate or incomplete. Consequently, we discontinued including coding information in our NCDs. However, the several NCDs that contained coding information remained in effect.

Further, section 522 of the Benefits Improvements and Protection Act (BIPA) of 2000 amended section 1869 of the Social Security Act regarding NCDs. Section 1869(f)(1)(B) addresses the issue of coding in NCDs as follows:

For purposes of this section, the term “national coverage determination” means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title, **but does not include a determination of what code, if any, is assigned to a particular item or service** covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered (emphasis added).

Although the statute does not explicitly exclude the use of codes in an NCD, it seems to support our current position that coding is more properly an operational issue and not appropriate to coverage determinations.

IV. Timeline of Recent Activities

From time to time, we have received phone inquiries regarding the coding information contained in the stem cell transplantation NCD. Consequently, on June 3, 2003 we opened an internally generated NCD request proposing to remove the CPT and ICD-9-CM codes from the NCD at 35-30.1 of the CIM. This was posted on the Internet at <http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=98>. We offered a 30-day period for public comments. At the end of the public comment period, July 3, 2003, we had not received any comments.

Since this is an internally generated request and there have been no comments from the public, external meetings have not been necessary.

V. FDA Status

Not Applicable

VI. CMS Analysis

As discussed above, the present coding in the stem cell transplant NCD is inaccurate or incomplete due to changes in the codes that have occurred over time. We also anticipate that there will be additional coding changes in the future, which will make it impractical to maintain such coding information in the NCD. Moreover, given the statutory definition of an NCD at Section 1869(f)(1)(B) of the Act, which excludes coding from the definition for appeals purposes, we believe it is appropriate to remove all coding information from the stem cell transplant NCD. Accordingly, we intend to issue a revised NCD that will remove all of the coding information from the current CIM section 35-30.1.

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